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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/441,966	11/17/1999	RODERICK L. HALL	98.736-A	5234

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EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 04/02/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/441,966

Applicant(s)

HALL ET AL.

Examiner

David J. Steadman

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Application Status***

The instant Office action is a supplemental restriction requirement. The previous Office action (Paper No. 11) was a restriction requirement of pending claims 1-18. Applicants' response did not include an election to a single invention as required by 37 CFR 1.143 and instead requested co-examination of all pending claims. It is noted that the restriction requirement of Paper No. 11 improperly included SEQ ID NO:49 in Groups II *and* VIII, that SEQ ID NO:49 does not appear in any of the claims of Group VIII (claims 1-10, 13, and 16-18), and that there is no Group X in the Groups of claims. Therefore, the examiner has re-restricted the claims in the instant supplemental restriction.

The instant supplemental restriction requirement is at the discretion of the examiner (see MPEP 802 and 37 CFR 1.142) and is deemed appropriate and necessary in view of the confusing nature of the initial restriction of Paper No. 11.

Claims 1-18 are pending in the application.

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claim(s) 1-11, drawn to a method of accelerating the rate of mucocilliary clearance by administering aprotinin, classified in class 514, subclass 2.
  - II. Claim(s) 1-10, 12, and 16-18, drawn to a method of accelerating the rate of mucocilliary clearance by administering the Kunitz-type inhibitor of SEQ ID NO:49, classified in class 514, subclass 2.
  - III. Claim(s) 1-10, 13, and 16-18, drawn to a method of accelerating the rate of mucocilliary clearance by administering the Kunitz-type inhibitor of SEQ ID NO:2, classified in class 514, subclass 2.

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- IV. Claim(s) 1-10, 13, and 16-18, drawn to a method of accelerating the rate of mucocilliary clearance by administering the Kunitz-type inhibitor of SEQ ID NO:45, classified in class 514, subclass 2.
- V. Claim(s) 1-10, 13, and 16-18, drawn to a method of accelerating the rate of mucocilliary clearance by administering the Kunitz-type inhibitor of SEQ ID NO:47, classified in class 514, subclass 2.
- VI. Claim(s) 1-10, 13, and 16-18, drawn to a method of accelerating the rate of mucocilliary clearance by administering the Kunitz-type inhibitor of SEQ ID NO:70, classified in class 514, subclass 2.
- VII. Claim(s) 1-10, 13, and 16-18, drawn to a method of accelerating the rate of mucocilliary clearance by administering the Kunitz-type inhibitor of SEQ ID NO:71, classified in class 514, subclass 2.
- VIII. Claim(s) 1-10, 14, and 16-18, drawn to a method of accelerating the rate of mucocilliary clearance by administering the Kunitz-type inhibitor of SEQ ID NO:4, classified in class 514, subclass 2.
- IX. Claim(s) 1-10, 14, and 16-18, drawn to a method of accelerating the rate of mucocilliary clearance by administering the Kunitz-type inhibitor of SEQ ID NO:5, classified in class 514, subclass 2.
- X. Claim(s) 1-10, 14, and 16-18, drawn to a method of accelerating the rate of mucocilliary clearance by administering the Kunitz-type inhibitor of SEQ ID NO:6, classified in class 514, subclass 2.
- XI. Claim(s) 1-10, 14, and 16-18, drawn to a method of accelerating the rate of mucocilliary clearance by administering the Kunitz-type inhibitor of SEQ ID NO:7, classified in class 514, subclass 2.

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- XII. Claim(s) 1-10, 14, and 16-18, drawn to a method of accelerating the rate of mucocilliary clearance by administering the Kunitz-type inhibitor of SEQ ID NO:3, classified in class 514, subclass 2.
  - XIII. Claim(s) 1-10, 14, and 16-18, drawn to a method of accelerating the rate of mucocilliary clearance by administering the Kunitz-type inhibitor of SEQ ID NO:50, classified in class 514, subclass 2.
  - XIV. Claim(s) 1-10, 14, and 16-18, drawn to a method of accelerating the rate of mucocilliary clearance by administering the Kunitz-type inhibitor of SEQ ID NO:1, classified in class 514, subclass 2.
  - XV. Claim(s) 1-10, 14, and 16-18, drawn to a method of accelerating the rate of mucocilliary clearance by administering the Kunitz-type inhibitor of SEQ ID NO:52, classified in class 514, subclass 2.
  - XVI. Claim(s) 1-10 and 15-18, drawn to a method of accelerating the rate of mucocilliary clearance by administering the Kunitz-type inhibitor of SEQ ID NO:8, classified in class 514, subclass 2.
- 2. The inventions are distinct, each from the other because:
  - 3. The methods of Groups I-XVI are independent as they utilize a structurally distinct Kunitz-type inhibitor.
  - 4. Because these inventions are distinct for the reasons given above and each of the inventions listed as Groups I-XVI requires a separate search, restriction for examination purposes as indicated is proper. "For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP 808.02" (see MPEP 803). The inventions listed as Groups I-XVI require divergent sequence searches, thus establishing the serious burden of search on the examiner.

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**Conclusion**

5. ***Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).***

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:30 am to 2:00 pm and from 3:30 pm to 5:30 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for this Group is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.

  
REBECCA E. PROUTY  
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